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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/937,730

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Mie Takahashi

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5291

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7590

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WENDEROTH, LIND & PONACK, L.L.P.  
2033 K STREET N. W.  
SUITE 800  
WASHINGTON, DC 20006-1021

EXAMINER

COUNTS, GARY W

ART UNIT

PAPER NUMBER

1641

DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/937,730

Applicant(s)

TAKAHASHI ET AL.

Examiner

Gary W. Counts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 5,12,27,31,41,45,49,53 and 60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 5,12,27,31,41,45,49,53 and 60 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Status of the claims**

The amendment filed December 7, 2005 is acknowledged and has been entered.

### ***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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4. Claims 5, 12, 27, 31, 41, 45, 53 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu (US 6,284,194) in view of Nanbu et al (US 6,130,055) or Uenoyama et al (US 5,856,117).

Chu discloses an analytical device and method of making the device. Chu teaches that the device comprises a porous reaction membrane and at least one receptor immobilized in a limited region (col 1, lines 40-50) (reaction layer and reactive components). Chu teaches applying a surfactant (surface active agent) to the reaction membrane and allowing to dry (col 1, lines 55-67). Chu teaches that drying can be performed by air drying at room temperature or by warm air with good ventilation (col 9, lines 30-43). Chu teaches the surfactant can be a surfactant such as polyoxyethylene (23), polyoxyethylene sorbitan monolaurate or polyoxyethylene sorbitan monooleate (col 8). Chu teaches that all or most of the surface (col 5, lines 27-32) is exposed to the surfactant.

Chu differs from the instant invention in failing to teach the surface active agent comprises a surface active agent having sugar in a hydrophilic part.

Nanbu et al disclose surfactants (surface active agent) used in bioassays. Nanbu et al disclose that the surfactant (surface active agent) can be polyoxyethylene sorbitan monolaurate, polyoxyethylene sorbitan monooleate, or sucrose monolaurate (contains sugar in hydrophilic part) (col 3, lines 26-35). Nanbu et al teaches that the use of a surfactant improves the assay sensitivity.

Uenoyama et al disclose surfactants (surface active agents) used in bioassays. Uenoyama et al disclose that the surfactant (surface active agent) can be

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polyoxyethylene (23), polyoxyethylene sorbitan monolaurate, polyoxyethylene sorbitan monooleate, n-octyl-B-D-thioglucoside (sugar in hydrophilic part) or sucrose monolaurate (contains sugar in hydrophilic part) (col 3, line 59 – col 4, line 13).

Uenoyama et al disclose that this surfactant improves the assay sensitivity.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute sucrose monolaurate surfactants (surface active agent) as taught by Nanbu et al for the surface active agent of Chu because Nanbu et al teaches that the use of a surfactant improves assay sensitivity. Further Chu teaches that polyoxyethylene sorbitan monolaurate and polyoxyethylene sorbitan monooleate are surfactants which can be used in the analytical device and the method of making the device and Nanbu teaches the equivalence of polyoxyethylene sorbitan monolaurate and polyoxyethylene sorbitan monooleate surfactants to sucrose monolaurate surfactants for their addition in bioassays and the selection to any known equivalents to replace the surfactants of Chu would be within the level of ordinary skill in the art and one of ordinary skill in the art would have a reasonable expectation of success using the surfactants (surface active agents) of Nanbu et al in the method and device of Chu.

It would have also been obvious to one of ordinary skill in the art at the time the invention was made to substitute the n-octyl-B-D-thioglucoside (sugar in hydrophilic part) or sucrose monolaurate surfactants (surface active agent) as taught by Uenoyama et al for the surface active agent of Chu because Uenoyama et al teaches that the use of a surfactant improves assay sensitivity. Further Chu teaches that polyoxyethylene

(23), polyoxyethylene sorbitan monolaurate and polyoxyethylene sorbitan monooleate are surfactants which can be used in the analytical device and the method of making the device and Uenoyama et al teaches the equivalence of polyoxyethylene (23), polyoxyethylene sorbitan monolaurate and polyoxyethylene sorbitan monooleate surfactants to sucrose monolaurate and n-octyl-B-D-thioglucoside surfactants for their addition in bioassays and the selection to any known equivalents to replace the surfactants of Chu would be within the level of ordinary skill in the art and one of ordinary skill in the art would have a reasonable expectation of success using the surfactants (surface active agents) of Uenoyama et al in the method and device of Chu.

With respect to claims 41 and 45 as recited in the instant claims. Chu teaches that drying can be performed by warm air in good ventilation. Therefore, Chu teaches drying moving air (wind) and thus Chu teaches wind drying as recited in the instant claims.

5. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Chu in view of Nanbu et al or Uenoyama et al as applied to claims 5, 12, 27, 31, 41, 45, 53 and 60 and further in view of Iwata et al (US 5,912,139).

See above for teachings of Chu, Nanbu et al and Uenoyama et al.

Chu, Nanbu et al and Uenoyama et al differ from the instant invention in failing to teach the reactive layer is dried by freeze drying.

Iwata et al disclose producing a test strip by impregnating a carrier with a solution comprising components. Iwata et al disclose that the impregnated carrier is then dried by freeze drying (col 6, lines 48-59). Iwata et al disclose that the components can be

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surfactants (col 6, lines 3-14 and col 10, lines 10-22). Iwata et al disclose that freeze drying thoroughly removes water from the carrier (col 6, line 53). Iwata et al disclose that this provides for a test strip, which provides high sensitivity and high accuracy measurement and excellent storage stability (abstract & col 2, lines 22-43).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate freeze drying as taught by Iwata et al into the modified method of Chu because Iwata et al teaches that freeze drying thoroughly removes water from the carrier and Iwata et al also teaches that this provides for a test strip which provides high sensitivity and high accuracy measurement and excellent storage stability.

### ***Response to Arguments***

6. Applicant's arguments filed December 7, 2005 have been fully considered but they are not persuasive.

Applicant argues that neither Tween20 nor TritonX100 are surface active agents which comprise a sugar in a hydrophilic part and are solidified when dried. Applicant states that both Tween20 and TritonX100 are also disclosed in the laundry list of surface active agents in the Chu reference. This is not found persuasive because as stated above and in the previous office action the Examiner has not relied upon Chu for teaching a surface active agent which comprises a sugar in a hydrophilic part and is solidified when dried.

Applicant argues that by using a surface active agent which is solidified when dried, the devitalization of the reactive component immobilized on the reactive layer can

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be minimized, thereby realizing enhanced preservation stability, extended quality maintenance period and extended storage condition. Applicant further states that by using a surface active agent which also comprises a sugar in a hydrophilic part, in addition to the advantages discussed above, the solubility is enhanced and the permeability is increased by the action of the sugar. Additionally, influence of the protein can be reduced and the denaturalization and devitalization of the immobilized protein can be minimized, therefore extending the performance of the reactive layer for a long time. Applicant states that on the contrary, in a conventional immunochromatography device, a surface active agent is generally employed only for improving permeability of the reaction layer. When a surface active agent which comprises no sugar in its hydrophilic part, and which is in a liquid state or in a paste-like state at normal temperature and normal pressure is employed, it is impossible to dry the surface active agent to an absolutely dry condition. Applicant further states that when a surface active agent which comprises no sugar in its hydrophilic part and which is in a liquid state or in a paste-like state at normal temperature and normal pressure is employed, it is impossible to provide a material with the high precision and high preservation stability of Applicant's claimed chromatography medium. This is not found persuasive for the following reasons (1) it appears that the Applicant is only arguing the reference of Chu and not arguing the combination of Chu and Nanbu and Uenoyama et al references and absent evidence to the contrary the combination of Chu and Nanbu, and the combination of Chu and Uenoyama et al possesses a surface active agent that is solidified when dried and which is a solid at normal temperature. (2) the fact that applicant has



recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious (see *Ex parte Obiaya*, 227 USPQ 58, 60 (Db. Pat. App. & Inter. 1985)).

Applicant argues that Nanbu provides a laundry list of surface active agents which includes all types of surfactants: ionic surfactants, ampholytic surfactants and nonionic surfactants and that Nanbu does not teach or suggest choosing a surface active agent which comprises sugar in a hydrophilic part and which is solidified when dried and that Nanbu clearly state that there is not limitation, whatsoever, on the surface active agent to be used. Applicant further, states that the Examiner has not provided a reason why one of ordinary skill in the art would select a particular surface active agent from the list provided in Nanbu et al, nor why one of ordinary skill in the art would select a surface active agent that is solidified when dried and comprises a sugar in a hydrophilic part. This is not found persuasive because as stated above and in the previous office action the Examiner has taken notice of the equivalence of sucrose monolaurate surfactant (contains a sugar in a hydrophilic part) (surface active agent) to polyoxyethylene sorbitan monolaurate and polyoxyethylene sorbitan monooleate which can be used in the analytical device and the method of making the device of Chu and further, that the surfactants are equivalents in bioassays. Further, as stated above and in the previous office action Nanbu teaches that the use of the surfactant provides the advantage of improves assay sensitivity. (It is noted that this advantage is the same as the advantage disclosed by Applicant on page 10, lines 12 and 13 "higher sensitivity"). Further, the

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selection of reagents can be affected by many factors such as the specific requirements of an assay, the availability of reagents as well as economic factors (i.e. the cost of reagents).

Applicant further argues that a surface active agent that is solidified when dried and comprises a sugar in a hydrophilic part results in advantage which are not present when a surface active agent comprising no sugar in a hydrophilic part, and which is in a liquid state or paste-like state at normal temperature and pressure is used. This is not found persuasive because the combination of Chu and Nanbu discloses a device and method of making the device and involves drying the device. The combination of Chu and Nanbu also teaches the device comprises a surfactant which would contain a sugar in the hydrophilic part. Thus absent evidence to the contrary the combination of Chu and Nanbu possess a surface active agent that is solidified when dried and which is a solid at normal temperature and normal pressure. With respect to the advantages as stated by Applicant above, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious (see *Ex parte Obiaya*, 227 USPQ 58, 60 (Db. Pat. App. & Inter. 1985)).

Applicant provides a discussion of Uenoyama et al and argues the specifics of the reaction system of Uenoyama et al. This is not found persuasive because the Examiner has not relied upon Uenoyama et al for the specifics of the reaction system but rather has relied upon Uenoyama et al for teaching that it is known in the art of bioassays that n-octyl-B-D-thioglucoside (surfactant with sugar in hydrophilic part) or

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sucrose monolaurate (surface active agent with sugar in hydrophilic part) (same surface active agents as disclosed by applicant on page 19, lines 21-22) is equivalent to surface active agent disclosed by Chu and that the selection to any known equivalents to replace the surfactants of Chu would be within the level of ordinary skill in the art.

Applicant further argues that a surface active agent that is solidified when dried and comprises a sugar in a hydrophilic part results in advantage which are not present when a surface active agent comprising no sugar in a hydrophilic part, and which is in a liquid state or paste-like state at normal temperature and pressure is used. This is not found persuasive because the combination of Chu and Uenoyama et al discloses a device and method of making the device and involves drying the device. The combination of Chu and Uenoyama also teaches the device comprises a surfactant which would contain a sugar in the hydrophilic part. Thus absent evidence to the contrary the combination of Chu and Uenoyama et al possess a surface active agent that is solidified when dried and which is a solid at normal temperature and normal pressure. With respect to the advantages as stated by Applicant above, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious (see *Ex parte Obiaya*, 227 USPQ 58, 60 (Db. Pat. App. & Inter. 1985)).

Applicant argues that the teachings of Iwata et al. do not remedy the deficiencies of Chu in view of Nanbu et al or Uenoyama et al. This is not found persuasive because as stated above, it is the Examiner's position that Chu in view of Nanbu or Uenoyama et

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al is appropriate and reads on the instantly recited claims. Therefore, the rejection based on combination of Iwata et al with Chu, Nanbu and Uenoyama et al is maintained and reads on the instantly recited claims.

***Conclusion***

7. No claims are allowed.
8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

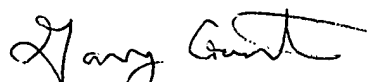
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gary Counts  
Examiner  
Art Unit 1641  
January 11, 2006



LONG V. LE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

01/16/06